EXHIBIT 50

From: Deborah Bearer </O=TEVA/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DBEARER>
To: Jeffrey Arcara
Sent: 6/3/2016 4:36:16 PM
Subject: FW: Thank You
Attachments: DeborahWBearer _2016_resume.docx; ISA Teva Vantrela ER Market Access Exec Summary 1.5.2016_george).pptx; V4V Sr Leadership_4_28_16_final.pptx; Vantrela Launch Plan Audit_ 052616.xls; Volume-for-Value White Paper_04_13_16_FINAL.pdf

Jeff –

Thanks again for your support. Had a good 1:1 with Marty this week. Hopefully things will move quickly… J

Have a great weekend,

Deb

Deb Bearer Director, Health Systems Marketing
NeuroPsych and Pain Care, Teva Pharmaceuticals 3E187
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deborah.bearer@tevapharm.com www.tevapharm.com

From: Deborah Bearer
Sent: Thursday, June 02, 2016 8:45 AM
To: Marty Berndt
Subject: Thank You

Marty –

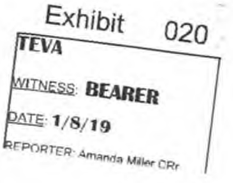
Thank you for the opportunity to meet yesterday to discuss your vision for Global Healthcare Ecosystems & Specialty Innovation. The team you are building is one that will be an asset to the organization and help to competitively advantage Teva within the ever changing healthcare environment. I look forward to further discussing how my background and experience can support you, the team and Teva.

As you suggested, I have attached a copy of my resume, along with a few examples of projects that provide some insight to my experience in building innovative strategic market access plans. I am currently supporting Migraine, Pain and Neuropsych pipeline and inline assets (Zecuity, TEV-48125 – migraine, cluster headache, Vantrela ER, AD IR Hydro and Oxy, Risperidone LAI, Funepide, AD Fentanyl Patch, Fentora, Nuvigil and Amrix.)

In addition to the attached, the following are projects associated with TEV-48125 (completed and on-going):

Migraine:

- Go-to-Market Strategy Workshop (GBT)
- Payer Value Story Development (PVT)
- AOP Planning – Payer Tactics -2016/17 (GBT)
- Brand Planning 2016 – US Region (GBT)
- Brand Positioning Workshop (GBT)
- Employer Strategy Development (PVT)
- Launch Sequencing Assessment – US/Canada – (PVT)
- Global Payer Pricing and Channel Research – (PVT)
- Migraine/Pain North Star Workshop – M.Derckacz
- Payer Agency of Record Assessment – (PVT)
- TEV-48125 War Games (GBT)



- PVT Roadmap Development (GLX/GHEOR)

Cluster Headache:

- Clinical Trial and pricing research
- AOP Planning

Once again, Marty, thank you for your time yesterday – hope to talk with you soon.

Best –

Deb

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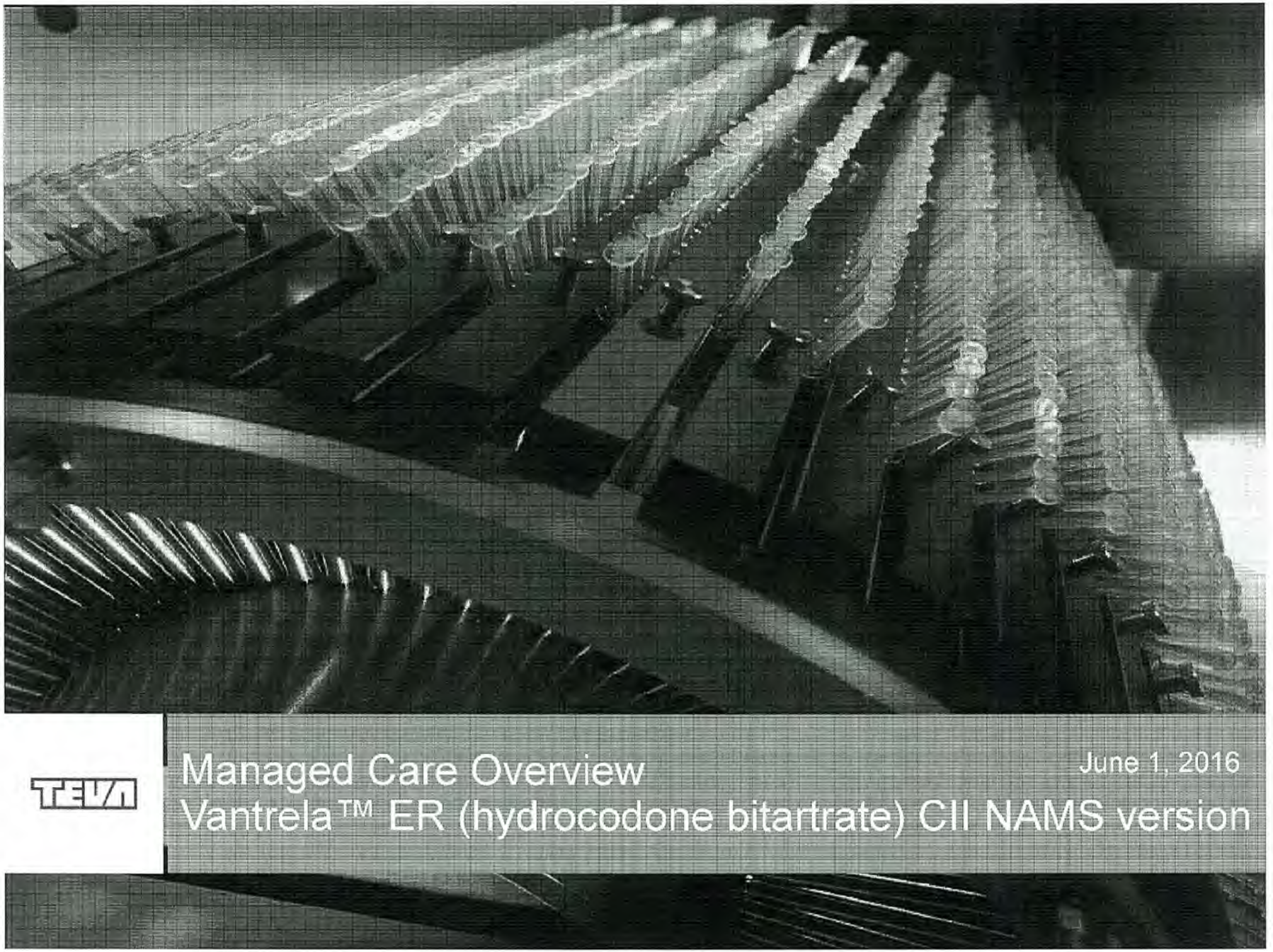

TEVA
Managed Care Overview
June 1, 2016
Vantrela™ ER (hydrocodone bitartrate) CII NAMS version

Background

- Long acting opioids are indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate
- For the purposes of this presentation, references from non cancer pain were used to extrapolate to the above indication and which is referred to as chronic pain in this presentation.

PLACEHOLDER

TEVA

INDICATIONS AND USAGE

VANTRELA™ ER (hydrocodone bitartrate) extended-release tablets CII is an opioid agonist indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve VANTRELA ER for use in patients for whom alternative treatment options (e.g., nonopioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- VANTRELA ER is not indicated as an as-needed (prn) analgesic.

IMPORTANT SAFETY INFORMATION

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; and CYTOCHROME P450 3A4 INTERACTION

Addiction, Abuse, and Misuse

VANTRELA ER exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing VANTRELA ER and monitor all patients regularly for the development of these behaviors or conditions.

Life-threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression may occur with use of VANTRELA ER. Monitor for respiratory depression, especially during initiation of VANTRELA ER or following a dose increase. Instruct patients to swallow VANTRELA ER tablets whole; crushing, chewing or dissolving VANTRELA ER tablets can cause rapid release and absorption of a potentially fatal dose of hydrocodone.

Accidental Ingestion

Accidental ingestion of even one dose of VANTRELA ER, especially by children, can result in a fatal overdose of hydrocodone.

Neonatal Opioid Withdrawal Syndrome

Prolonged use of VANTRELA ER during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

Cytochrome P450 3A4 Interaction

The concomitant use of VANTRELA ER with all cytochrome P450 3A4 inhibitors may result in an increase in hydrocodone plasma concentrations, which could increase or prolong adverse drug effects and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in hydrocodone plasma concentration. Monitor patients receiving VANTRELA ER and any CYP3A4 inhibitor or inducer.

Chronic pain: current landscape

Chronic pain has a high prevalence[1]

- >100 million adult sufferers in the US
- More than total affected by heart disease, cancer, and diabetes combined

Chronic pain places a substantial economic burden[2]

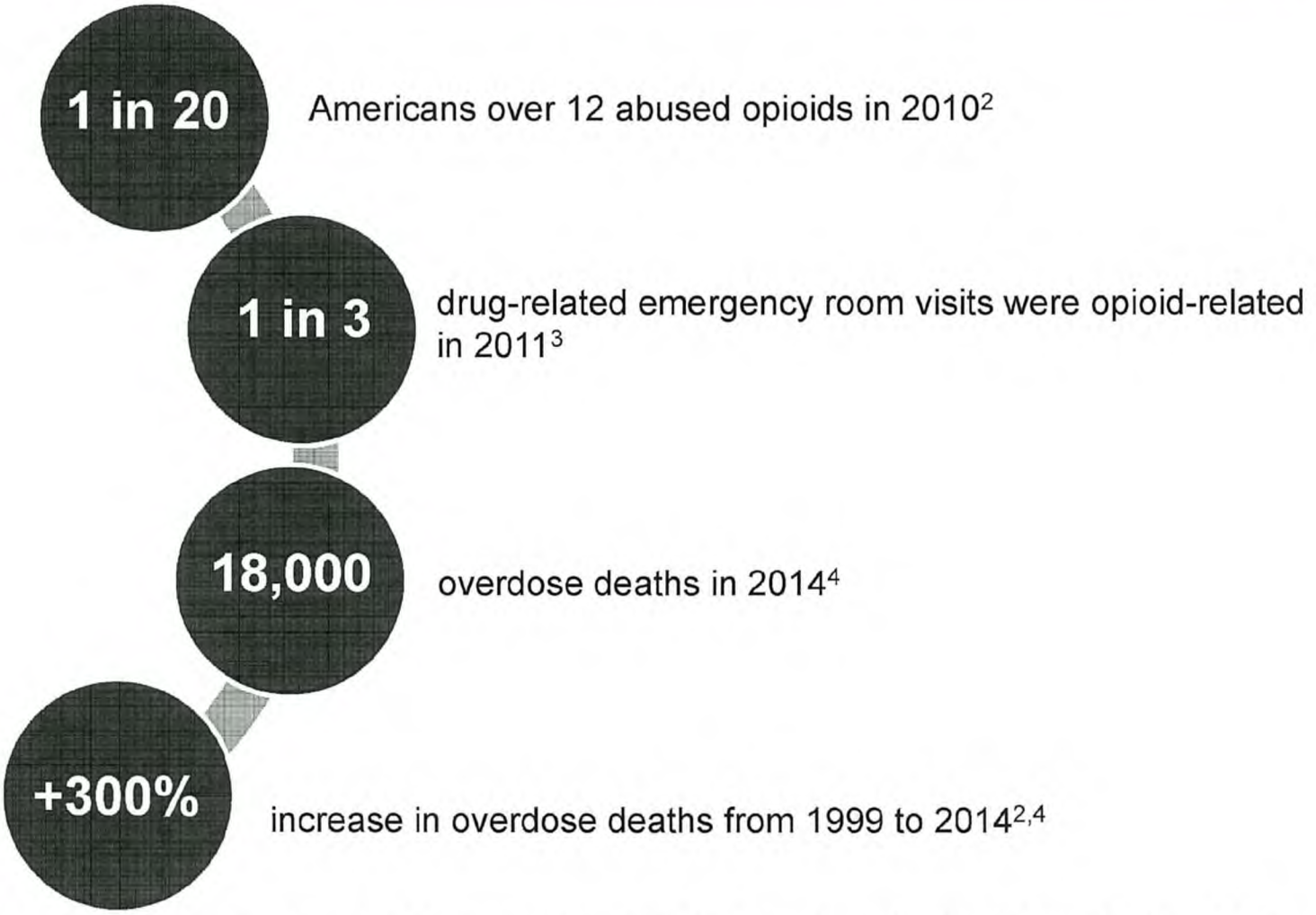
- $261-300 billion in pain related health care costs
- More than annual costs of cancer ($243 billion) and diabetes ($188 billion) but comparable to heart disease($309 billion)

Available non-opioid treatments do not provide adequate pain relief in some chronic pain patients

- <50% chronic pain patients achieve adequate pain relief with current treatments[3,4]
- Opioids may be effective and appropriate for some patients
- Long-acting opioids are recommended for the management of pain severe enough to require daily, around-the-clock, long-term treatment and for which alternative treatment options are inadequate[5]

1. IOM. https://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research/Pain%20Research%202011%20Report%20Brief.pdf. Accessed April 14, 2016. **2.** Gaskin DJ, et al. *J Pain*. 2012;13(8):715-724. **3.** Conaghan PG, et al. *Rheumatology*. 2015;54:270-277. **4.** Zielger D. *Diabetes Care*. 2009;32(2):S414-S419. **5.** Fine PG, et al. *Pain Med*. 2009;10 Suppl 2:S79-S88.

The misuse, abuse, and diversion of opioids is a major public health concern[1]



1. ALEC. https://www.alec.org/app/uploads/2016/01/2016-ALEC-State-Factor-Optimizing-the-Abuse-deterrent-Opioids-Market-Final.pdf. Accessed April 1, 2016. **2.** CDC. http://www.cdc.gov/vitalsigns/pdf/2011-11-vitalsigns.pdf. Accessed May 14, 2016. **3.** SAMHSA. http://archive.samhsa.gov/data/2k13/DAWN2k11ED/DAWN2k11ED.htm. Accessed May 17, 2016. **4.** CDC. http://www.cdc.gov/nchs/data/health_policy/AADR_drug_poisoning_involving_OA_Heroin_US_2000-2014.pdf. Accessed April 28, 2016.

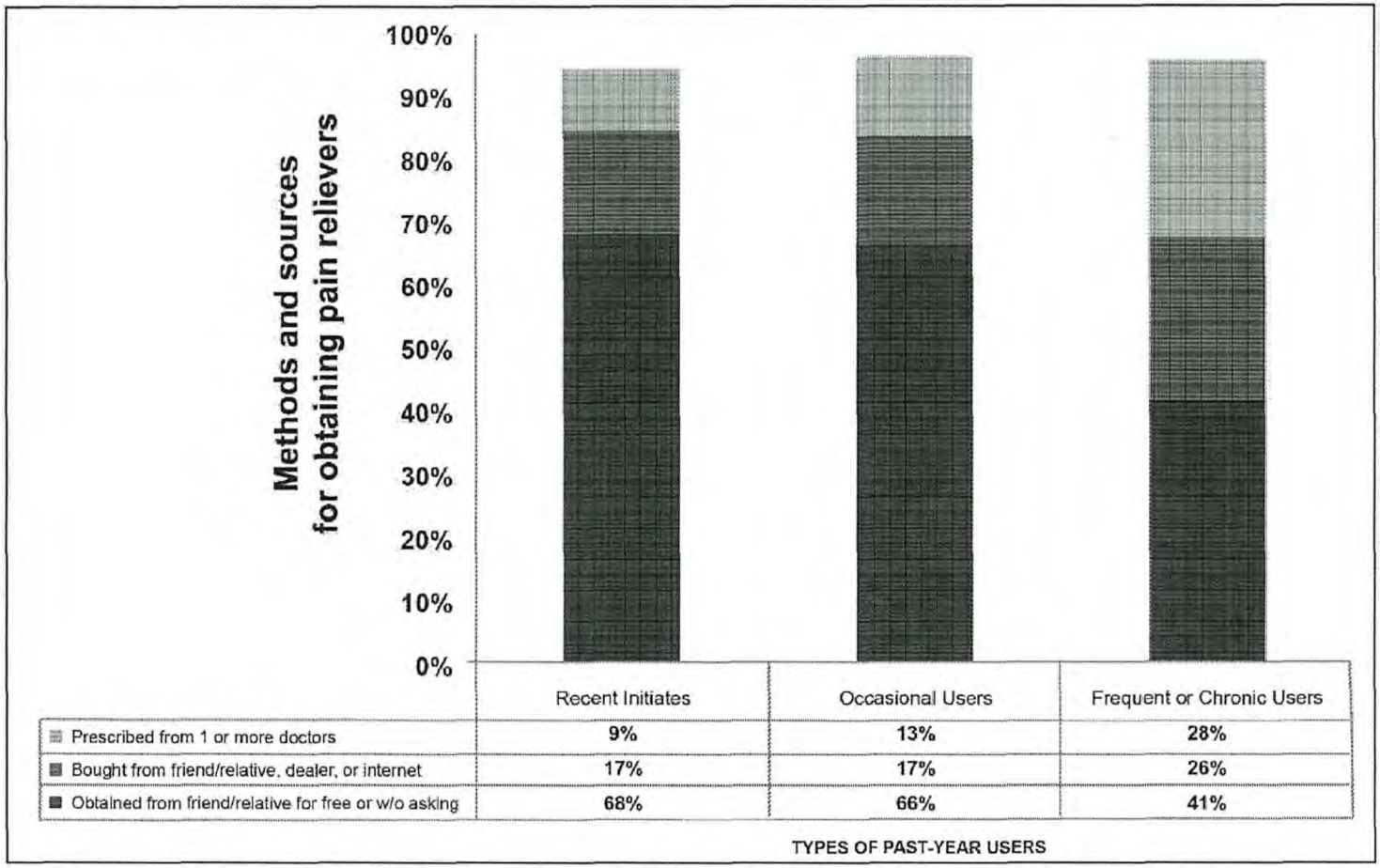
Definitions related to opioid use

Abuse	Use of opioid medication for non-medical reasons
Diversion	Illicit transfer of legally prescribed pain medications to someone other than the patient
Misuse	Use of opioids contrary to instructions, regardless of harmful or adverse effects

ACPM. http://c.ymcdn.com/sites/www.acpm.org/resource/resmgr/timetools-files/painmedsclinicalreference.pdf. Accessed May 14, 2016.

Sources of diversion vary, with the majority obtaining pain relievers for non-medical use from friends and relatives

How Different Misusers of Pain Relievers Get Their Drugs

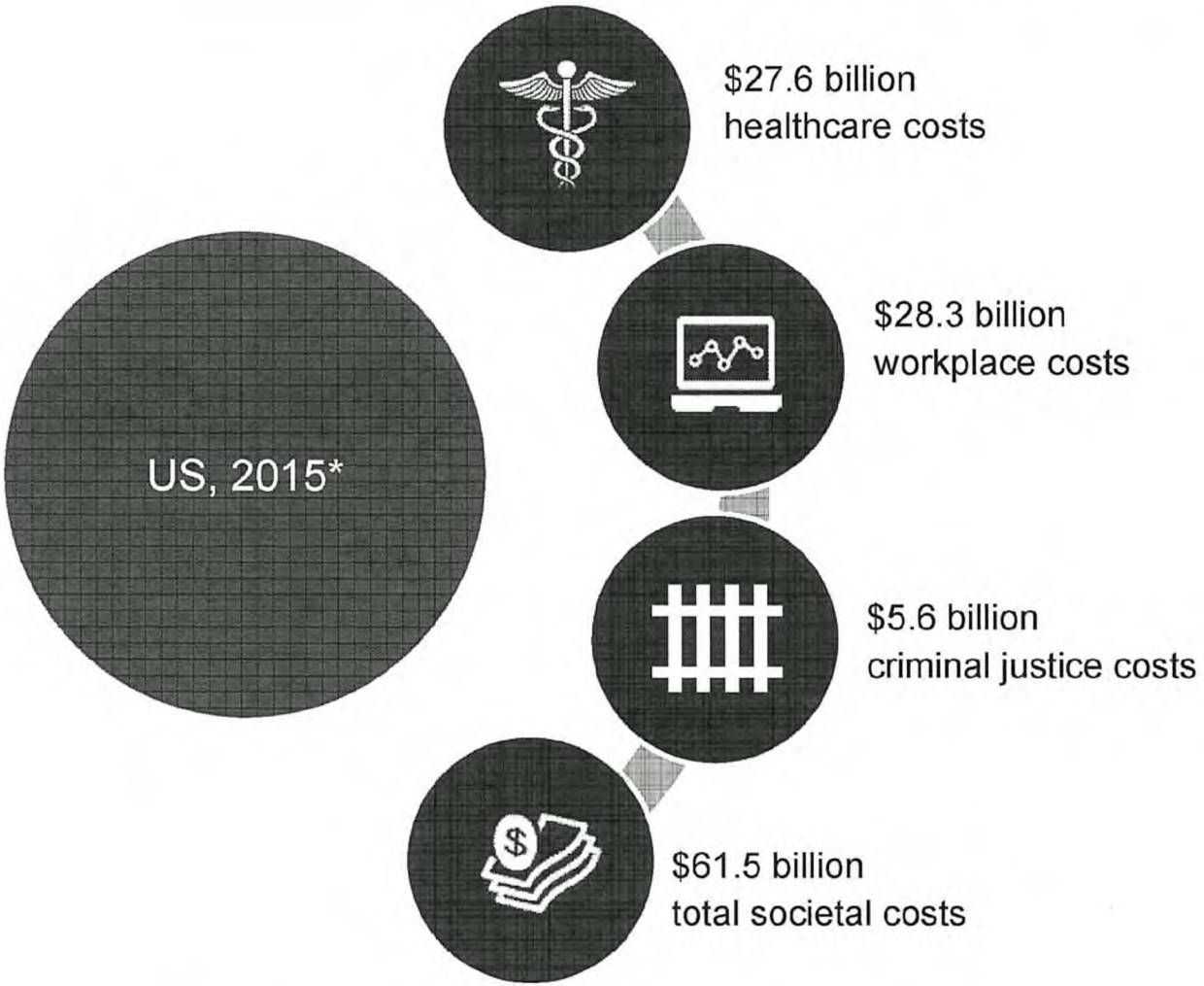


	Recent Initiates	Occasional Users	Frequent or Chronic Users
Prescribed from 1 or more doctors	9%	13%	28%
Bought from friend/relative, dealer, or internet	17%	17%	26%
Obtained from friend/relative for free or w/o asking	68%	66%	41%

Source: SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2009-2010.

White House. http://www.whitehouse.gov/sites/default/files/ondcp/Fact_Sheets/opioids_fact_sheet.pdf. Accessed May 14, 2016.

Opioid abuse poses a substantial economic burden



Birnbaum HG, et al. *Pain Med.* 2011;12(4):657-667.

*Adjustment from 2009 to 2015 USD using Consumer Price Index inflation rates from Bureau of Labor Statistics: http://www.bls.gov/data/inflation_calculator.htm. Accessed May 16, 2016.

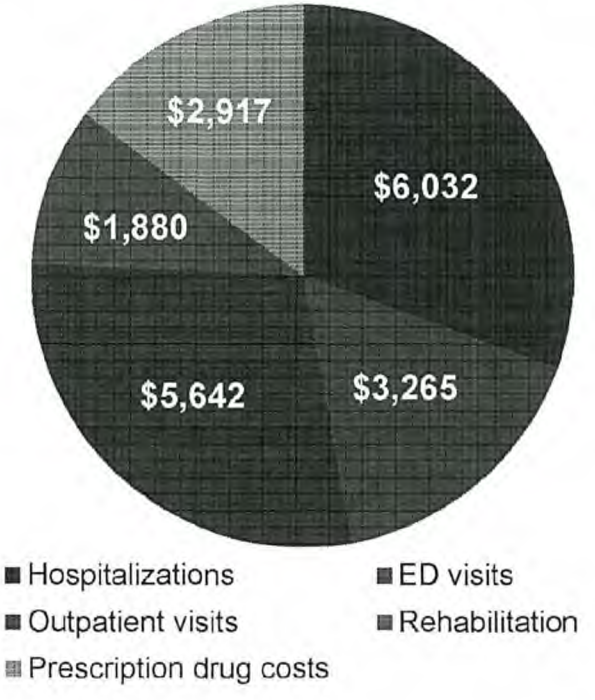
Healthcare resource use and costs for opioid abusers are significantly higher than for non-abusers

~$ 11,000 (2.1x) more total annual healthcare costs*
High costs driven by hospitalization, outpatient, and emergency room visits

Difference in Annual Healthcare Resource Use between abusers and non-abusers

- 4.9x more inpatient days
- 3.1x more emergency department (ED) days
- 1.4x more outpatient visits
- 31.2x more rehabilitation facility days
- 1.4x more prescriptions filled

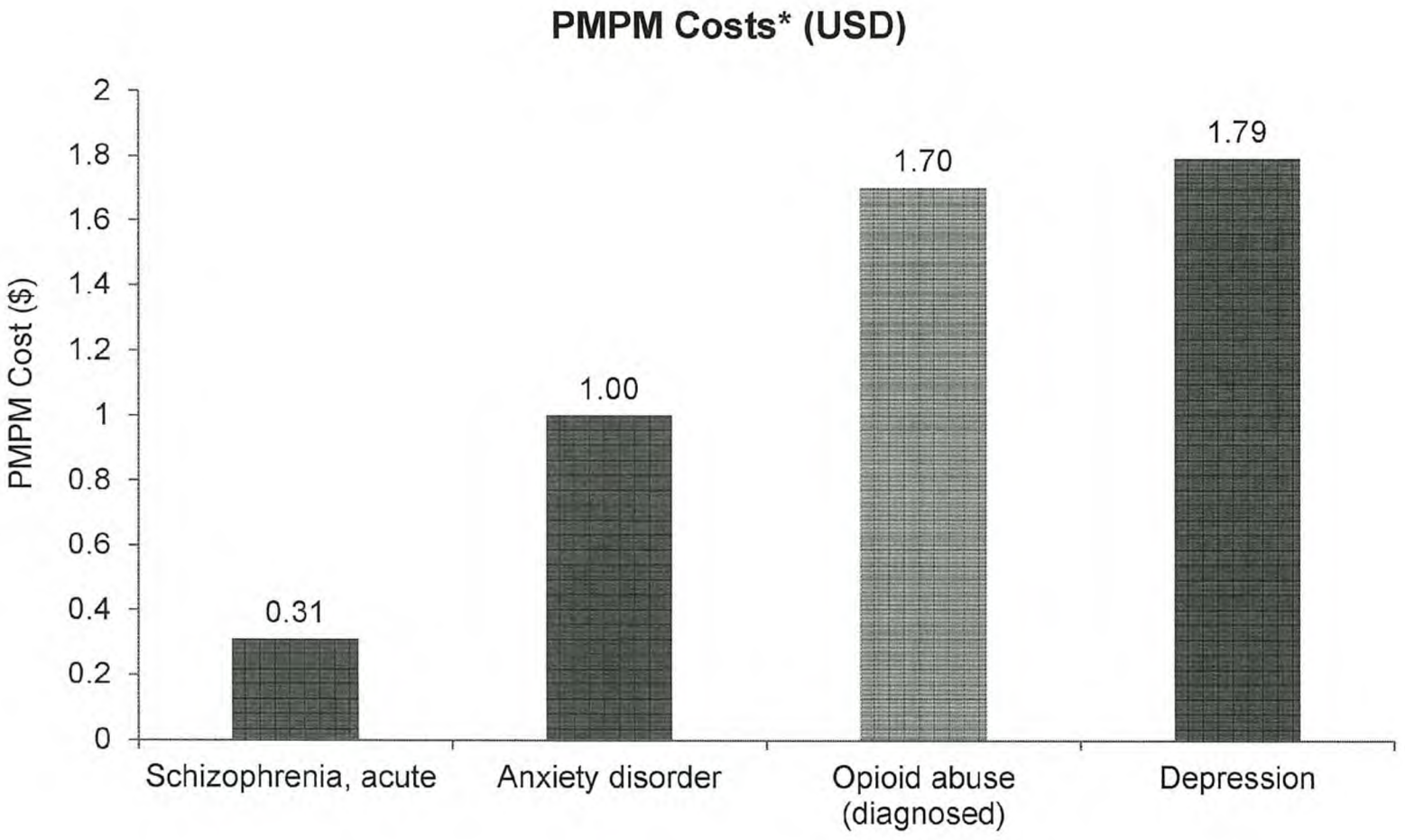
Mean Annual Costs* for Opioid Abusers



Rice JB, et al. *Appl Health Econ Health Policy*. 2014;12:435-446.

*Adjustment from 2012 to 2015 USD using consumer price inflation rates from Bureau of Labor Statistics: http://www.bls.gov/data/inflation_calculator.htm. Accessed May 16, 2016.

On a per-member per-month (PMPM) basis, healthcare costs of opioid abuse are comparable to some mental health conditions

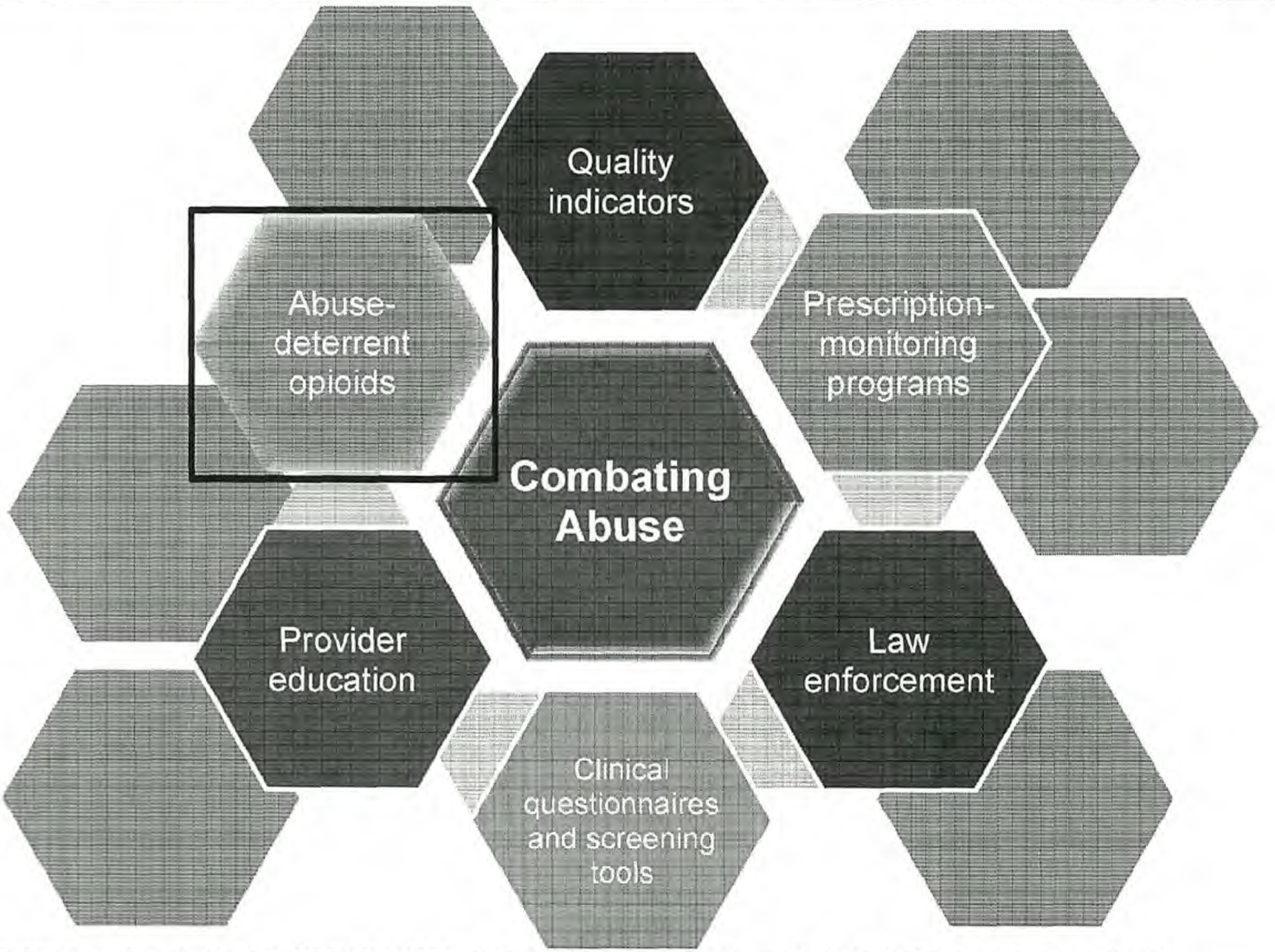


Rice JB, et al. *Appl Health Econ Health Policy*. 2014;12:435-446.

*Adjustment from 2012 to 2015 USD using Consumer Price Index inflation rates from Bureau of Labor Statistics: http://www.bls.gov/data/inflation_calculator.htm. Accessed May 16, 2016.

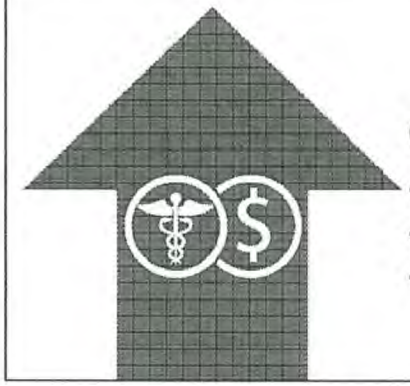
COMBATING OPIOID ABUSE: A PLACE FOR ABUSE-DETERRENT OPIOID FORMULATIONS

Combating opioid abuse requires a multi-pronged effort, and the use of abuse-deterrent formulations of opioids is one such approach



ALEC. https://www.alec.org/app/uploads/2016/01/2016-ALEC-State-Factor-Optimizing-the-Abuse-deterrent-Opioids-Market-Final.pdf. Accessed April 1, 2016.

Some evidence exists on opioid abuse deterrence and potential cost savings with abuse deterrent formulations[1]



Opioids have a high rate of abuse and generate enormous costs

- Almost 12% of opioid patients become addicted[2]
- Opioids are responsible for approximately 2/3 of drug overdose deaths[3]
- Abuse leads to billions of dollars in healthcare and indirect costs[4-7]

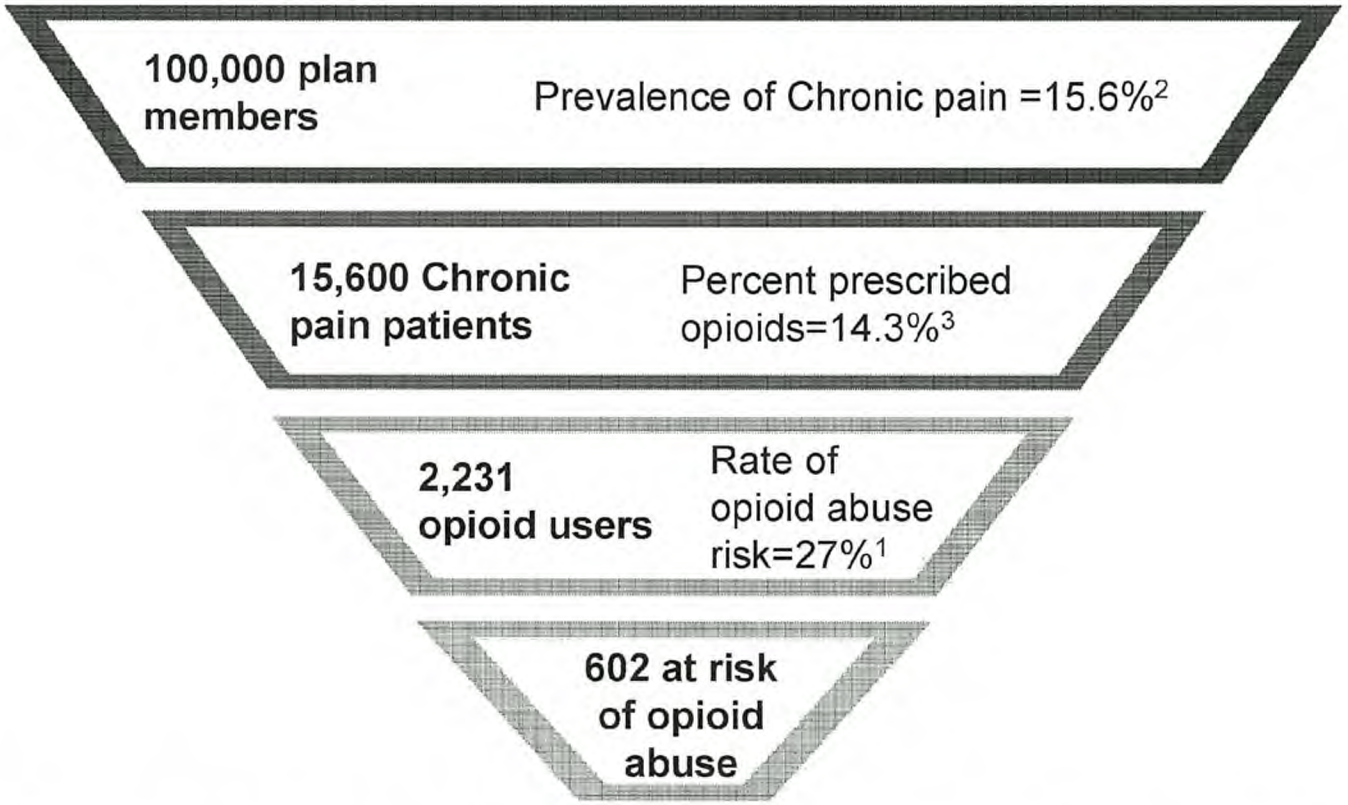
ADFs can deter abuse and have potential for cost savings

- Some evidence on abuse deterrence exists[1]
- The introduction of ADFs reduced direct and indirect costs in the US by more than $1 billion[8]

1. ALEC. https://www.alec.org/app/uploads/2016/01/2016-ALEC-State-Factor-Optimizing-the-Abuse-deterrent-Opioids-Market-Final.pdf. Accessed April 1, 2016. **2.** Vowles KE, et al. *Pain*. 2015;156(4):569-576. **3.** CDC. http://www.cdc.gov/mmwr/pdf/wk/mm6450.pdf. Accessed May 17, 2016. **4.** Birnbaum HG, et al. *Pain Med*. 2011;12(4):657-667. **5.** Meyer R, et al. *Popul Health Manag*. 2014;17(6):372-387. **6.** Baser O, et al. *Pain Practice*. 2014;14(5):437-445. **7.** Hansen RN, et al. *Clin J Pain*. 2011;27(3):194-202. **8.** Kirson NY, et al. *Pain Med*. 2014;15:1450-1454.

Appropriate use of abuse deterrent formulations may help reduce some of the opioid abuse risk

The at-risk subpopulation within chronic pain is estimated to be ~27% or 602 members per 100,000 plan members[1]



1. Coutinho AD, et al. Opioid abuse among long-term opioid users with chronic non-cancer pain. Accepted at World Institute of Pain, 2016. New York, USA.
2. Riskowski JL. *Pain Med*. 2014;15(9):1508-1521. 3. Rasu RS, et al. *J Pain*. 2013;4(6):568-578.

Identification criteria for at risk groups are not robust due to non-availability of some individual patient measures in administrative claims data

TEVA

Four at-risk groups were identified among opioid users with chronic pain based on dose, age, and days supply of opioid therapy

Group	Opioid Dose (mg/day MED)*	Age (years)	Total Days Supply of Opioids
1	>62.3	≤46.5	-
2	>62.3	>46.5	≥328
3	≤62.3	≤34.5	-
4	≤62.3	34.5–46.5	>364

*MED – morphine equivalent dosing

Clinicians are most suited to make individual patient-level decisions and determine suitable opioid therapy for appropriate patients based on variety of clinical and other relevant factors

Coutinho AD, et al. Opioid abuse among long-term opioid users with chronic non-cancer pain. Accepted at World Institute of Pain, 2016. New York, USA.

PLACEHOLDER

An Opioid **Designed** to Help You Manage the Many Intricacies of Chronic Pain[2]

- **12-hour dosing for pain severe enough to require around-the-clock pain management**[2]
- **Consistent with known safety profile of hydrocodone**[1,*]
- **Triple-layer CIMA ADT™, an abuse deterrence technology designed to resist common methods of abuse**[1]
- **Available in 5 dosage strengths (broad total daily dose, 30-180 mg/day)**[1,**]
- **Demonstrated efficacy**[2]
- **Acetaminophen free**[2]

ADT=abuse-deterrence technology.

*VANTRELA ER 90 mg tablets, a single dose greater than 60 mg, or a total daily dose greater than 120 mg, are only for use in patients in whom tolerance to an opioid of comparable potency has been established.

IMPORTANT SAFETY INFORMATION (continued)

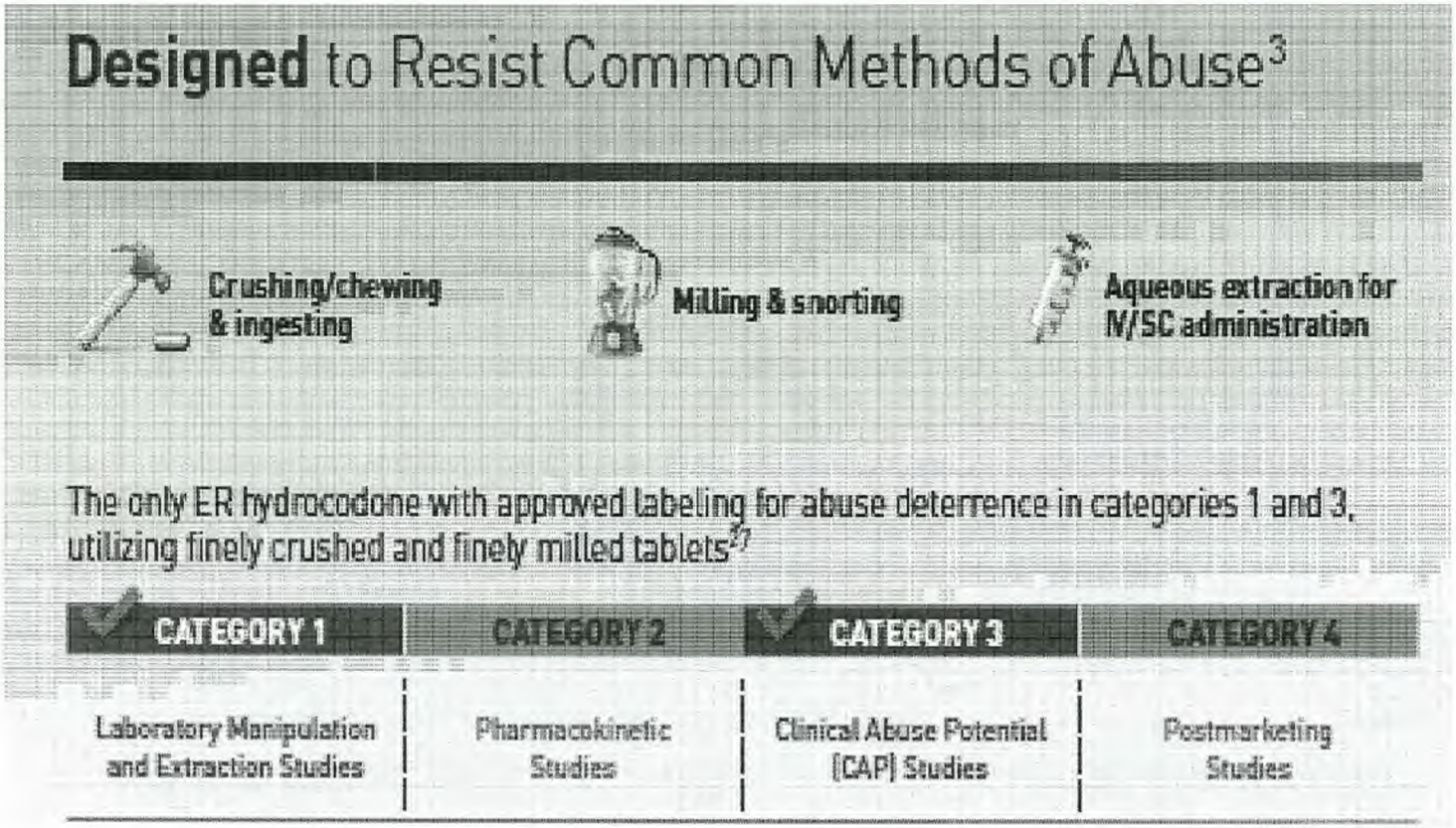
VANTRELA ER is contraindicated in patients with:

- Significant respiratory depression
- Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment
- Known or suspected paralytic ileus and GI obstruction
- Hypersensitivity (e.g., anaphylaxis) to hydrocodone bitartrate or any other ingredients in VANTRELA ER

Interactions with Central Nervous System Depressants: Hypotension, profound sedation, coma, respiratory depression and death may result if VANTRELA ER is used concomitantly with alcohol or other central nervous system (CNS) depressants (e.g., sedatives, anxiolytics, hypnotics, neuroleptics, other opioids). If co-administration is required, consider a dose reduction of one or both drugs and monitor patients for signs of sedation and respiratory depression.

DRAFT. FOR INTERNAL DISCUSSION. NOT FOR DISTRIBUTION

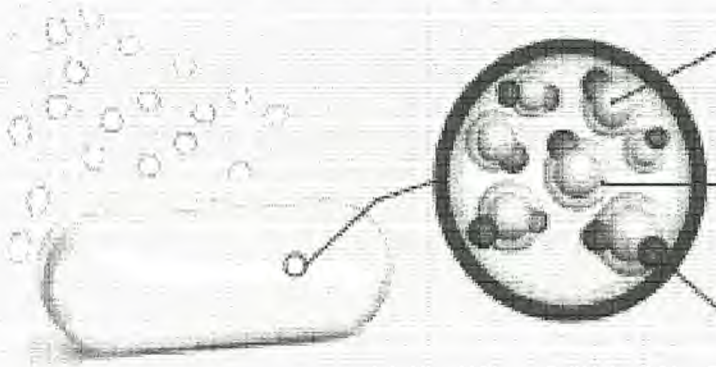
PLACEHOLDER



PLACEHOLDER

Comprehensive abuse deterrence data > > >

The first and only ER hydrocodone designed with **triple-layer CIMA ADT™ (abuse deterrence technology)**[1]



Layer 1 Gel core helps resist drug particle extraction

Layer 2 Polymer coating makes it difficult to break or crush drug particles

Layer 3 Additional polymers further resist crushing and extraction

IV=intravenous.
SC=subcutaneous.

IMPORTANT SAFETY INFORMATION (continued)

Use in Patients with Head Injury and Increased Intracranial Pressure: Monitor patients closely who may be susceptible to the intracranial effects of CO_2 retention, such as those with evidence of increased intracranial pressure or impaired consciousness. Opioids may obscure the clinical course of a patient with a head injury. Avoid the use of VANTRELA ER in patients with impaired consciousness or coma.

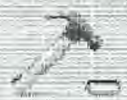
Use in Patients with Gastrointestinal Conditions: VANTRELA ER is contraindicated in patients with known or suspected paralytic ileus. Monitor for decreased bowel motility in post-operative patients receiving opioids. Monitor patients with biliary tract disease, including acute pancreatitis.

Avoidance of Withdrawal: When discontinuing VANTRELA ER, gradually taper the dose. Do not abruptly discontinue VANTRELA ER.

PLACEHOLDER

Designed for Low "Likeability" in Nondependent, Recreational Opioid Users as Demonstrated in Studies[1,2*]

Clinical Abuse Potential (CAP) studies conducted with rigorous opioid extraction methods to reduce particle size in oral and intranasal administration



Finely crushed oral administration[1,2*†‡]

- **Significantly lower peak liking and overall drug-liking scores** vs IR hydrocodone (P<0.001)
- **Significantly lower Take Drug Again scores** vs IR hydrocodone (P<0.001)

Finely milled intranasal administration[1,2*†§]

- **Slower rise in liking score, with significantly lower peak drug liking and overall drug-liking scores** vs IR hydrocodone (P=0.004)
- **Significantly lower abuse potential than Zohydro® ER based on peak drug liking and overall drug-liking scales** (P<0.001)
- **Significantly lower Take Drug Again scores for finely milled intranasal VANTRELA ER** vs IR hydrocodone and Zohydro® ER (P=0.005 and P<0.001, respectively)

*Drug liking was measured on a bipolar drug-liking scale of 0 to 100 by nondependent, recreational opioid abusers where 50 represents a neutral response, 0 represents maximum disliking, and 100 represents maximum liking.[2]
†Response to whether the subject would take the study drug again was measured on a unipolar scale of 0 to 100 where 0 represents the strongest negative response (definitely would not take drug again) and 100 represents the strongest positive response (definitely would take drug again).[2]
‡The abuse potential of finely crushed oral VANTRELA ER was assessed in healthy, nondependent recreational opioid users in a single-dose, randomized, double-blind, triple-dummy, active- and placebo-controlled crossover study (placebo: n=42; IR hydrocodone powder: n=39; VANTRELA ER crushed: n=42).[2]
§The abuse potential of finely milled intranasal VANTRELA ER was assessed in healthy, nondependent recreational opioid users in a single-dose, randomized, double-blind, quadruple-dummy, active- and placebo-controlled crossover study (placebo: n=34; IR hydrocodone powder: n=34; Zohydro® ER milled: n=34; VANTRELA ER milled: n=34).[2]

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PLACEHOLDER

The Majority of Patients Experienced a Clinically Meaningful Response to Therapy[1,2]*

Defined as at least a 30% reduction in weekly average of daily worst pain intensity (wWPI), which is the benchmark typically used in opioid clinical trials[1,2]

PERCENT IMPROVEMENT IN wWPI SCORE FROM SCREENING TO FINAL VISIT AT WEEK 12*

≥30% REDUCTION

57% of patients taking VANTRELA ER (n=191)

vs

P<0.001

45% of patients taking placebo (n=180)

During the double-blind treatment period, 136 (71%) patients in the hydrocodone treatment group and 145 (81%) patients in the placebo treatment group took rescue medication[1]

- Daily mean rescue medication usage[1]
  - —0.8 to 1.6 tablets for the VANTRELA ER group
  - —1.2 to 1.9 tablets for the placebo group

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PLACEHOLDER

Safety Profile as Observed in Clinical Trials[2]

ADVERSE DRUG REACTIONS DURING THE DOUBLE-BLIND, POST-TITRATION TREATMENT PERIOD IN 2 STUDIES[2]

	Placebo N=326 n(%)	VANTRELA ER N=337 n(%)
Nausea	23 (7)	39 (12)
Constipation	15 (5)	46 (14)
Headache	16 (5)	21 (6)
Somnolence	3 (<1)	9 (3)
Vomiting	11 (3)	17 (5)
Dizziness	5 (2)	6 (1)
Pruritus	3 (<1)	5 (1)
Fatigue	4 (1)	7 (2)
Dry mouth	2 (<1)	6 (1)
Diarrhea	10 (3)	12 (4)
Insomnia	9 (3)	4 (1)
Anxiety	5 (2)	13 (4)

* Consistent with the known safety profile of hydrocodone[2,4]

• Acetaminophen-free pain relief

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PLACEHOLDER

Important Safety Information

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; and CYTOCHROME P450 3A4 INTERACTION

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Life-threatening Respiratory Depression
Serious, life-threatening, or fatal respiratory depression may occur with use of VANTRELA ER. Monitor for respiratory depression, especially during initiation of VANTRELA ER or following a dose increase. Instruct patients to swallow VANTRELA ER tablets whole; crushing, chewing or dissolving VANTRELA ER tablets can cause rapid release and absorption of a potentially fatal dose of hydrocodone.

Accidental Ingestion
Accidental ingestion of even one dose of VANTRELA ER, especially by children, can result in a fatal overdose of hydrocodone.

Neonatal Opioid Withdrawal Syndrome
Prolonged use of VANTRELA ER during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

Cytochrome P450 3A4 Interaction
The concomitant use of VANTRELA ER with all cytochrome P450 3A4 inhibitors may result in an increase in hydrocodone plasma concentrations, which could increase or prolong adverse drug effects and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in hydrocodone plasma concentration. Monitor patients receiving VANTRELA ER and any CYP3A4 inhibitor or inducer.

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- Hypersensitivity (e.g., anaphylaxis) to hydrocodone bitartrate or any other ingredients in VANTRELA ER

Interactions with Central Nervous System Depressants: Hypotension, profound sedation, coma, respiratory depression and death may result if VANTRELA ER is used concomitantly with alcohol or other central nervous system (CNS) depressants (e.g., sedatives, anxiolytics, hypnotics, neuroleptics, other opioids). If co-administration is required, consider a dose reduction of one or both drugs and monitor patients for signs of sedation and respiratory depression.

Use in Elderly, Cachectic, and Debilitated Patients: Life-threatening respiratory depression is more likely to occur in elderly, cachectic, or debilitated patients as they may have altered pharmacokinetics or altered clearance compared to younger, healthier patients. Monitor such patients closely.

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PLACEHOLDER

Important Safety Information (continued)

Use in Patients with Chronic Pulmonary Disease: Monitor patients with significant chronic obstructive pulmonary disease or cor pulmonale, and patients having a substantially decreased respiratory reserve, hypoxia, hypercapnia, or preexisting respiratory depression, as even usual therapeutic doses of VANTRELA ER may decrease respiratory drive to the point of apnea. Consider the use of alternative non-opioid analgesics in these patients if possible.

Hypotensive Effect: VANTRELA ER may cause severe hypotension including orthostatic hypotension and syncope in ambulatory patients. Monitor patients for signs of hypotension after initiating or titrating the dose of VANTRELA ER. Avoid the use of VANTRELA ER in patients with circulatory shock.

Use in Patients with Head Injury and Increased Intracranial Pressure: Monitor patients closely who may be susceptible to the intracranial effects of CO_2 retention, such as those with evidence of increased intracranial pressure or impaired consciousness. Opioids may obscure the clinical course of a patient with a head injury. Avoid the use of VANTRELA ER in patients with impaired consciousness or coma.

Use in Patients with Gastrointestinal Conditions: VANTRELA ER is contraindicated in patients with known or suspected paralytic ileus. Monitor for decreased bowel motility in post-operative patients receiving opioids. Monitor patients with biliary tract disease, including acute pancreatitis.

Avoidance of Withdrawal: When discontinuing VANTRELA ER, gradually taper the dose. Do not abruptly discontinue VANTRELA ER.

Driving and Operating Machinery: VANTRELA ER may impair the mental and physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery. Warn patients not to drive or operate dangerous machinery unless they are tolerant to the effects of VANTRELA ER and know how they will react to the medication.

Common Adverse Reactions: Adverse reactions in ≥2% of patients in placebo-controlled trials include nausea, constipation, headache, somnolence, vomiting, dizziness, pruritus, fatigue, dry mouth, diarrhea, insomnia, and anxiety.

Interactions with Mixed Agonist/Antagonist Opioid Analgesics: Mixed agonist/antagonist (i.e., pentazocine, nalbuphine, butorphanol) and partial agonist (buprenorphine) analgesics may reduce the analgesic effect of hydrocodone or precipitate withdrawal symptoms. Avoid the use of mixed agonist/antagonist and partial agonist analgesics in patients receiving VANTRELA ER.

Monoamine Oxidase Inhibitors (MAOI): VANTRELA ER is not recommended for use in patients who have received MAO inhibitors within 14 days as severe and unpredictable potentiation by MAO inhibitors has been reported with opioid analgesics.

Pregnancy: Based on animal data, VANTRELA ER may cause fetal harm. VANTRELA ER should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: Because of the potential for serious adverse reactions in infants, nursing mothers should stop nursing or discontinue VANTRELA ER after consulting their doctor.

Hepatic or Renal Impairment: In patients with moderate to severe hepatic or renal impairment, start with the 15 mg dose of VANTRELA ER. Monitor these patients closely for adverse events such as respiratory depression.